

### REMARKS

Claims 1-21 are active. Claims 1 and 3 are rejected under 35 USC 103 as being unpatentable over Tapper. Applicant notes with appreciation that claims 2, and 4-11 are deemed to contain allowable subject matter and claims 12-21 are allowed. The drawings filed on April 9, 2004 are accepted.

Enclosed is a second copy of the Notice of References Cited form PTO 892 taken from the parent application of the present application. A copy of this form was filed in the previously filed response to the prior Office Action on April 9, 2004. The Examiner was previously requested to make these references of record in the instance case. This was not done. The Examiner is once again respectfully requested to acknowledge he has reviewed the cited references by initially this form and forward a copy with his acknowledgement to the applicant as required by the rules. No copies of the references need be provided according to the rules, MPEP 609I.A.2. This form is filed herewith so that the references will be printed in the patent document for the instant application.

Applicant traverses the rejection of claim 1 over Tapper ('367). Claim 1 is directed to a bunion correction device for the small toe in a foot. This involves the application of an electrical signal to the digiti minimi brevis muscle to counter balance the strength of the foot flexor digitorum muscle to correct the bunion condition of the small toe.

The above-noted Office Action dated July 2, 2004 states that Tapper discloses "a bunion correction device comprising means for attaching at least one electrode to the foot for applying an electrical signal . . ." This statement is not correct. Tapper does not disclose a bunion correction device. Means for applying at least one electrode to the foot

for administering iontophoretic treatment to the foot is not a means for correcting bunion conditions, much less the condition claimed in claim 1. This treatment is disclosed as an ion surface treatment and not a muscle stimulation which are different, and much less a muscle treating device for a bunion condition.

The closest that Tapper comes to applying electrical signals to a foot is applying the signals to the plantar [the sole] surface of the foot, col. 2, lines 40-42, col. 6, lines 15-17, for administering iontophoretic treatment to the foot. This is a surface treatment of the skin as disclosed by this reference. Simply because the foot is involved does not imply that the bunion condition is being treated. Tapper does not go so far. He describes iontophoretic treatment to cause ionized molecules to be driven through the skin for introducing moisture or medicaments into the skin (col. 1, lines 13-18). Iontophoretic treatment of the skin is foreign to treating or affecting muscles. This treatment introduces ions into the skin as explained by Tapper.

Tapper discusses an article by Levitt at col. 2, lines 33-42. Here he states the article discloses the use of an electrode placed in water to cover the palm or sole (of the foot) (this is the plantar region discussed by Tapper at col. 2, line 43 and col. 6, line 16). This treatment is to inhibit perspiration (col. 1, line 41). Tapper is interested in limiting the treatment only to the skin surface area of the body being treated as would be performed by a person on himself, col. 1, lines 55-64, to avoid disrupting normal function of vital body organs.

Therefore, Tapper is only concerned with iontophoretic treatment of skin surfaces and is not concerned with muscle stimulation, much less with a device as claimed in claim

1. Iontophoresis is related to the introduction into the tissues medication by means of ions of a given medicament. See *Illustrated Stedman's Medical Dictionary*, 24<sup>th</sup> Edition, 1982, at p. 725. Thus in the most general sense iontophoresis is concerned with introduction of ions into the skin surface and not with stimulation of the underlying muscles. One is foreign to the other.

Even assuming arguendo iontophoresis is used to stimulate muscles, which it is not as discussed above, Tapper is silent as to stimulating certain muscles of the foot as claimed to overcome the bunion condition of the small toe of the foot. Tapper's discussion of treating the sole of a foot is foreign to treating a bunion condition. The sole is not a small toe. Contrary to the position of the Office Action, Tapper has no support for treating the bunion condition of the small toe as claimed. Any such correlation is gleaned improperly from applicant's disclosure. This is a hindsight rejection which is proscribed.

The Office Action does not cite a single reference that discloses that the source of the bunion condition is due to muscle unbalance and if such unbalance does exist, which muscles are involved. The Tapper references does not go so far. Thus the conclusion of the Office Action does not follow the precedent mandated by the MPEP.

Reference is made to Exhibit A of applicant's prior response which states that a bunion is the painful deformity of the big toe caused by shoes that bend this toe inward toward the smaller toes, putting pressure upon the joint connecting the big toe with the foot. An illustration shows that the condition is corrected by surgery requiring a bone to be removed. This teaches away from what is claimed, the antithesis of obviousness.

Thus it was not recognized by the prestigious University of Pennsylvania medical staff that the bunion condition is a result of or could be the result of muscle unbalance as taught by the present inventor. This belies any conclusion that it would be obvious to one of ordinary skill to do what is claimed, since one of ordinary skill would not use electrical stimulation, but surgery to correct the bunion condition. The level of skill of a person of ordinary skill in the art is also presumed to be one who thinks along the line of conventional wisdom and is not one who undertakes to innovate, whether by patient, systematic research or extraordinary insights, it makes no difference which. Phillips Petroleum v. U.S. Steel, 6 USPQ 2d 1065 (D. Ct. Del. 1987). (Citing cases). The present claimed invention thus goes against the conventional wisdom of others of ordinary skill in the podiatry art and thus is not obvious to such persons.

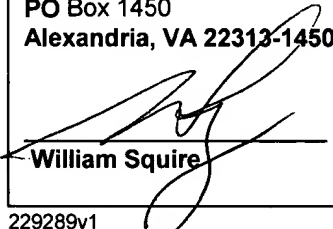
Reference is also made to Exh. B of applicant's prior response stating that Dr. Hillstrom met with the present inventor regarding the subject claimed invention. Dr. Hillstrom states that FES (functional electrical stimulation) has been used for a wide variety of applications including treating paralyzed individuals, for pain management, for delivering pharmaceutical agents transdermally (for administering iontophoretic treatment to the skin as disclosed by Tapper) as discussed above and so on.

Claim 1 is not for generally applying signals to the foot, nor to the skin for administering iontophoretic treatment to the foot, which has numerous muscles, but to specific muscles. No reason is given as to why it is obvious to apply the signals as claimed to specific muscles. The Office Action is silent to this. This is not a proper basis for the rejection.

Discovering the source of the problem is part of the invention of a whole that needs to be considered. The problem is bunions. Tapper is not concerned with this problem. MPEP 2141.02, page 2100-120, 121. The knowledge that generally electrical signals can treat skin with ions is of no help in this context. The reference does not teach or suggest what is claimed. Claim 1 is believed allowable.

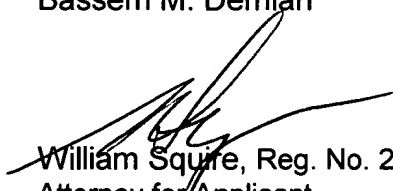
Claims 2-11 depend from claim 1 and are believed allowable for at least the same reasons in addition to the fact that except for claim 3, the remaining claims depending from claim 1 are deemed to contain allowable subject matter.

If any fee is due for this paper, the Commissioner is authorized to charge deposit account 03-0678 with respect to any underpayments or to credit that deposit account for any overpayments.

<b><u>FIRST CLASS CERTIFICATE</u></b>	
I hereby certify that this correspondence is being deposited today with the U.S. Postal Service as First Class Mail in an envelope addressed to:	
Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450	
 William Squire	<u>August 13, 2004</u> Date

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